### PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

See form PCT/SA/220  WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)  Date of mailing (day/month/year) see form PCT/SA/210 (second sheet)  POR FURTHER ACTION See paragraph 2 below  International application No. PCT/SB/2004/004362  International papilication No. PCT/SB/2004/004362  International Patent Classification (IPC) or both national classification and IPC A61N5/06  Applicant  EUPHOTONICS LIMITED  1. This opinion contains indications relating to the following items:  Box No. II Priority  Box No. II Priority  Box No. IV Lack of unity of invention  Box No. V. V. Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement  Box No. VI Certain documents cited  Box No. VIII Certain defects in the international application  Box No. VIII Certain observations on the international application  FURTHER ACTION  If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the international Bureau under Trule 66. Lb/s(b) that written opinions of this international Searching Authority will not be so considered.  If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/SA/220.	То:					PCT
International application No. PCT/GB2004/004362 International filing date (day/month/year) Priority date (day/month/year) 15.10.2004 International application No. PCT/GB2004/004362 International Patent Classification (IPC) or both national classification and IPC A61NS:06 Applicant EUPHOTONICS LIMITED  1. This opinion contains indications relating to the following items:    Box No. I Basis of the opinion   Box No. II Priority Box No. II Priority Box No. II Priority Box No. II Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Box No. IV Lack of unity of invention Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement   Box No. VI Certain documents cited Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application Box No. VIII Certain observations on the international application If a demand for international Preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.  If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220.	see form PCT/ISA/220				INTERNATION (F	NAL SEARCHING AUTHORITY PCT Rule 43 <i>bis</i> .1)
PCT/GB2004/004362   15.10.2004   16.10.2003     International Patent Classification (IPC) or both national classification and IPC     A61N5.06   Applicant     EUPHOTONICS LIMITED	· · · · · · · · · · · · · · · · · · ·					
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# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2004/004362

	Box No. I	Basis of the opinion
1.	With regard the language	to the <b>language</b> , this opinion has been established on the basis of the international application in e in which it was filed, unless otherwise indicated under this item.
	languag	inion has been established on the basis of a translation from the original language into the following , which is the language of a translation furnished for the purposes of international search Rules 12.3 and 23.1(b)).
2.	With regard necessary to	to any <b>nucleotide and/or amino acid sequence</b> disclosed in the international application and othe claimed invention, this opinion has been established on the basis of:
	a. type of m	aterial:
	□ a se	quence listing
	□ table	e(s) related to the sequence listing
	b. format of	material:
	□ in w	ritten format
	☐ in co	omputer readable form
	c. time of fili	ng/furnishing:
	□ cont	ained in the international application as filed.
	☐ filed	together with the international application in computer readable form.
	☐ furn	shed subsequently to this Authority for the purposes of search.
3.	has bed copies	ion, in the case that more than one version or copy of a sequence listing and/or table relating thereto en filed or furnished, the required statements that the information in the subsequent or additional is identical to that in the application as filed or does not go beyond the application as filed, as riate, were furnished.

4. Additional comments:

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2004/004362

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability							
	The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:						
(	the entire international application	the entire international application,					
1	☑ claims Nos. 23, 24, 27, 30, 31,	claims Nos. 23, 24, 27, 30, 31, 32					
ı	because:						
1	the said international applicatio matter which does not require a	the said international application, or the said claims Nos. 23, 24, 27, 30, 31 relate to the following subject matter which does not require an international preliminary examination (specify):					
	see separate sheet	see separate sheet					
	the description, claims or drawi unclear that no meaningful opin	the description, claims or drawings (indicate particular elements below) or said claims Nos. 32 are so unclear that no meaningful opinion could be formed (specify):					
	see separate sheet	see separate sheet					
ļ	the claims, or said claims Nos. could be formed.	principles of the first and to made quality cappoints by the decomption that he meaning at opinion					
1	no international search report has been established for the whole application or for said claims Nos. 23, 24, 27, 30, 31, 32						
d	the nucleotide and/or amino ac C of the Administrative Instruct	the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:					
	the written form	☐ has not been furnished					
		☐ does not comply with the standard					
	the computer readable form	☐ has not been furnished					
		☐ does not comply with the standard					
	the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.						
	☐ See separate sheet for further	etails					

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2004/004362

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

26, 28

No: Claims

1-22, 25, 29

Inventive step (IS)

Yes: Claims

No: Claims

1-22, 25, 26, 28, 29

Industrial applicability (IA)

Yes: Claims

1-22, 25, 26, 28, 29

No: Claims

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

#### Re Item III.

1. The method claims 23, 24, 27, 30, 31 relate to a method for treatment of the human or animal body by therapy and/or surgery. Acne vulgaris (page 1, line 12) is a disease, the same applies for skin ulcers and skin cancers (page 10, lines 21-24). Hence, a method directed to the treatment of such conditions has essentially a therapeutical character. The additional cosmetic effects are regarded as a bonus effect. Note also that it is impossible to separate between "cosmetic" and "therapeutic" effects when applying radiation.

In addition, the <u>partial ablation</u> referred to on page 3, lines 1-6 and the <u>killing of hair cells</u> (page 10, lines 17-21) relates to a method for treatment by surgery.

Therefore, no preliminary international examination is required for the subject-matter of these method claims (see Article 34 (4) (a) (i) PCT and Rule 67.1 (iv) PCT).

- 2. Claims 26, 28, 29 are only examined insofar as they relate to the cosmetic treatment of teeth (whitening).
- 3. Claim 32 only contains a global reference to the drawings (PCT Rule 6.2a). Hence, any intended limitation of subject matter is not clear, contrary to the requirements of Article 6 PCT, and an opinion in the sense of Article 33 PCT is not possible.

#### Re Item V.

- 1 The following documents are referred to in this communication:
  - D1: FR-A1-2 591 902 (COLLIN YVON) 26 June 1987 (1987-06-26)
  - D2: US-A-5 616 140 (PRESCOTT ET AL) 1 April 1997 (1997-04-01)
  - D3: GB-A-2 356 570 ( OE-LYS LIMITED; ADRIAN CLIFFORD WARBURTON; DEREK ALFRED WALTER B) 30 May 2001 (2001-05-30)
  - D4: US-B1-6 616 447 (RIZOIU IOANA M ET AL) 9 September 2003 (2003-09-09)

#### 2 INDEPENDENT CLAIM 1

2.1 The objection of Item VIII notwithstanding, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses all the features of claim 1 (the references in parentheses applying to this document):

An apparatus (see figures 1 and 3) for illuminating a zone of mammalian skin, the apparatus comprising:

- a light emitter (9);
- an applicator (3) movable to direct light emitted from the light emitter to the zone of mammalian skin; and
- a controller (1) controlling the duration and/or intensity of light delivered to the surface of the skin to provide a desired effect without producing significant ablation of the mammalian skin (this is evident since the laserdiodes are intended for therapeutical purposes, see D1: abstract, last sentence).

Furthermore, the subject matter of claim 1 is considered to lack novelty over at least documents D2 (see figures 1-3 and column 4, lines 55-67 as well as column 5, lines 1-10), D3 (see claim 17: "hand held applicator" and pages 4 and 5), and D4 (see column 4, lines 18-22 and column 5, lines 5-18 and column 8, lines 24-38).

#### 3. DEPENDENT CLAIMS 2-22

Dependent claims 2-22 do not contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty (Article 33(2) PCT) since the features defined therein are known from one or more of the documents D1-D4:

3.1 Claims 2-5: A suction cup having a reflective inner surface is already known from D1 (see page 6, lines 7-11).

- 3.2 Claims 6, 7: An adhesive layer is disclosed in D2, see column 12, lines 1-4. Furthermore, the light emitter of D2 is also attached to said layer in the sense of claim 7.
- 3.3 Claim 8: The use of a topical agent is obvious in combiation with the device of D2 since D2 refers to PDT (claim 14, lines 64-65) that requires an agent. An agent on the applicator is also known from document D4 (column 6, line 58 column 7, line 12).
- 3.4 Claims 9-11: D1 discloses a plurality of light emitters, which are laser diodes that emit in the infrared range (page 4, lines 35-38).
- 3.5 Claims 12, 13: A wavelength of 570-590 nm is disclosed in D3 (see page 4, last line).
- 3.6 Claim 14: The light emitter (9) of D1 is received in the applicator (3), see D1: figure 3.
- 3.7 Claim 15: The controller (1) of D1 has a housing.
- 3.8 Claim 16: Any light emitter evidently requires a power source.
- 3.9 Claim 17: rechargeable batteries are known from D2: see column 6, lines 11-25 and column 7, lines 47-57.
- 3.10 Claims 18-22: the device of D2 comprises a timer as defined in claim 18: see column 6, lines 37-51. Said timer is able to provide the timing intervals as defined in claims 19-21 and is also able to inhibit the duration of the period of light above a predetermined time as referred to in claim 22.

#### 4. METHOD CLAIM 25

The use of a light applicator for treatment of the teeth i.e. whitening them is already disclosed in D4, see column 4, lines 3-7. Hence, method claim 25 lacks novelty over D4 (Article 33(2) PCT).

- 5. DEPENDENT CLAIMS 26, 28, 29
- 5.1 The duration of the time of treatment of the teeth as defined in claims 26 and 28 is a normal value for the person skilled in the art. Hence, the subject matter of claims 26 and 28 lacks an inventive step (Article 33(3) PCT) over D4.
- 5.2 The wavelength range of 400-1000 nm for treatment of the teeth is already known from D4 (see column 4, lines 31-33). Hence, the subject matter of claim 29 lacks novelty over D4 (Article 33(2) PCT).

#### Re Item VIII

#### Certain observations on the international application

- 1. Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. This relates in particular to feature c) "to provide a desired effect without producing significant ablation of the mammalian skin".
- 2. The vague and imprecise statement in the description on page 11 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.